PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/P33145	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/12508	International filing date *(day/month/year)* 05.11.2003	Priority date *(day/month/year)* 07.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.05.2004	31.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/12508

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-22 as originally filed

Claims, Numbers

1-36 as originally filed

Drawings, Sheets

1/15-15/15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 36

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 36

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	22, 33-35
	No:	Claims	1-21, 23-32
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-35
Industrial applicability (IA)	Yes:	Claims	1-35
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 36 was not searched in view of Article 17(2)(a)(ii) PCT and therefore no substantive examination can be performed.
The subject-matter of this claim referred solely to the content of the drawings, which is not allowable under Article 34(4)(a)(ii) PCT.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

The document WO-A-9856444 discloses (the references in parentheses applying to this document):

a holder for holding a dispensing container system (2, 8) which is adapted to dispense a quantity of a fluid contained therein on movement thereof relative to the holder and further includes a dispensing counter means (13) for counting the number of quantities of the fluid dispensed,
the holder having a moulded plastic body (1) with inner and outer surfaces, the inner surface bounding a cavity adapted to receive the dispensing container system (2, 8) in movable relation thereto, the cavity having moulded counter advance means (17) adapted in use to cooperate with the dispensing counter means (13) on relative movement between the dispensing container system (2, 8) and the body (1) to advance the dispensing counter means to indicate the dispensing of a quantity of the fluid, wherein the body is formed with an outlet port () in communication with the cavity such that the fluid dispensed from the dispensing container system (2, 8) is dischargeable there through, and wherein an aperture (20) extends through the body (1) from the outer surface to the inner surface in alignment with the counter advance means (17)

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

Dependent claims 2-35 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

Claims 2-4, 11, 15, 19-21, 24, 30:
The features of these claims relate to the counter and its advance means. These features have already been disclosed in WO-A-9856444, in combination with a display portion for the counter. The above claims are therefore not new (Article 33(2) PCT).

Claims 5-10, 12, 23:
The features of these claims relate to the shape of (components of) the dispensing container system in order to avoid unwanted rotations. The shape of the counter and holder disclosed in WO-A-9856444 performs the same function. Claims 5-10 and 12 are therefore not new (Article 33(2) PCT)

Claims 13-14 and 16-18:
Document WO-A-9856444 anticipates the outlet of the metered dose inhaler to be designed as a nozzle for insertion into the patient's nostril (page 8, lines 8-11). Claims 13 and 14 are therefore not new (Article 33(2) PCT). Claims 16 to 18 relate to standard properties of an outlet, and are therefore not new (Article 33(2) PCT).

The feature of forming the holder by means of injection moulding (claim 22) does not involve an inventive step (Article 33(3) PCT), as this is a common way of forming plastic objects, such as inhalers.

Claims 25-29, 31 and 32 are not new (Article 33(2) PCT), as they relate to standard features of a container member, disclosed in WO-A-9856444.

Claims 34, 35:
Placing an inhaler in a separate outer part is known to the skilled person, see document WO-A-02/00281. Claims 34 and 35 therefore do not involve an inventive step (Article 33(3) PCT).

The features of claim 33 relate to the method of manufacturing of the inhaler. As such, this claim should be reformulated to describe a method of manufacturing rather than a device.
None of the prior art documents mentions the mould parts involved in the manufacturing of the inhaler. However, based on known mould design procedures, it is

more than likely that the mould part involved in creating aperture 20, disclosed in document WO-A-9856444, had a function in the moulding of the counter advance means. Therefore, It is considered that claim 33 does not involve an inventive step (Article 33(3) PCT),

The device disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met.

Claims 2 to 35 depend from claim 1 and refer to further embodiments of the device described in claim 1 and thus meet the requirements of Article 33(4) PCT for the same reasons explained above.

Re Item VI
Certain documents cited

The following documents were published later, but filed earlier than the filing date of the application in suit. They do not constitute prior art for the purposes of Article 33(2) PCT, but are cited under Rule 70.10 PCT.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
EP-A-1369139	10.12.2003	03.06.2002	03.06.2002
WO-A-04/001664	31.12.2003	19.06.2003	21.06.2002